HLAaccuTest™ All & EasyHLAanalyzer™

- NGS panel kit & analysis software for high-resolution HLA-typing
- Comprehensive primer coverage for 11 HLA loci, based on IMGT/HLA database: HLA-A, B, C, DRB1/3/4/5, DQB1, DPB1, DQA1 and DPA1
- Superior analysis software: easy-to-use, user-friendly UI and intuitive operation
- Reduced ambiguity rate through expanded target region design
- Advanced accuracy by the improvement of allele balance through the optimization of panel design and experimental condition

Working Process

HLAaccuTest™ All

Ordering Information

Products	Cat. No.	Quantity	Storage
HLAaccuTest™ All & EasyHLAanalyzer™	NGB151V-024	24	-20°C
	NGB151V-096	96	

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All-in-One NGS solution for HLA typing

Specification of NGS panel kit

HLAaccuTest™ All	
Specimen	gDNA from blood or bone marrow aspirate
Input DNA conc.	50 – 100 ng/locus
DNA library prep method	Amplicon (Long-range PCR)
Duration time of DNA library prep.	9~11 hrs (hands on time: 3~4 hrs)
Target HLA locus	Class I: A, B, C Class II: DRB1/3/4/5, DQA1, DQB1, DPA1 and DPB1
Target region	A, B, C / DQA1, DQB1, DPA1, DPB1: entire exon & intron region DRB1/3/4/5: exon 2, 3, 4 & intron region
Target size	55.6 Kb
Ambiguity rate	< 0.2%
Sequencing platform	MiSeq / MiSeqDx
Sequencing reagent	MiSeq Reagent Nano Kit, v2: 6 samples, minimum 200X/locus MiSeq Reagent Micro Kit: 24 samples, minimum 200X/locus
Data analysis solution	EasyHLAanalyzer™

Performance of HLAaccuTest™ All

Clinical validity assessment

Evaluated clinical validity of HLAaccuTest™ All using residual clinical samples identified genotypes with IVD approved product (Sanger Sequencing Based Typing)

The overall Concordance rate for the tested clinical samples is 99.7%, met the acceptance criteria

HLA Locus	# of samples	# of alleles	Concordance (%)
All alleles	165	1650	99.8 (1646/1650)*
HLA-A	165	330	99.7 (329/330)**
HLA-B	165	330	100 (330/330) #
HLA-C	165	330	99.7 (329/330)**
HLA-DRB1	165	330	99.4 (328/330) ##
HLA-DQB1	165	330	99.7 (329/330)**

* All: 95% CI, 99.38~99.93% ** HLA-A, C, DQB1: 95% CI, 98.32~99.99%
# HLA-B: 95% CI, 98.89~100% ## HLA-DRB1: 95% CI, 97.83~99.93%

Accuracy comparison assessment

Evaluated accuracy of HLAaccuTest™ All by comparing with IVD approved Next Generation Sequencing based product using standard material identified genotypes

Concordance rate is 100%, met the acceptance criteria

HLA Locus	# of samples	# of alleles	Concordance (%)
All alleles	96	960	100%*
HLA-A	96	192	100%**
HLA-B	96	192	100%**
HLA-C	96	192	100%**
HLA-DRB1	96	192	100%**
HLA-DQB1	96	192	100%**

* All alleles: 95% CI, 99.77~100%
** HLA-A, B, C, DRB1, DQB1: 95% CI, 98.89~100%

Analysis workflow & features

1 Sequencing using NGS instruments
Generate FASTQ files and export

- Provides clinical reports and auto analysis of HLA typing through software (reports: pdf & word file)
- Analysis available in user PC without extra analysis sever
- Develops analysis pipeline optimized for the HLAaccuTest™ All
- Accurate results comparison between donor and recipient through IMGT* database version selection function when analyzing results
- Provides IMGT database update information timely
- Provides the function reporting newly discovered alleles
- Provides various information including Korean SNP frequency
- Manufactured from GMP/ISO 13485 certified facility

* The international ImMunoGeneTics information system®

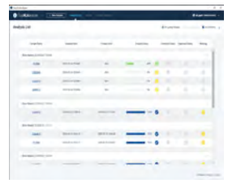
2 Request for analysis from user PC
Auto analysis with EasyHLAanalyzer™

3 Create clinical result report

EasyHLAanalyzer™ process

Login

Uploading



- Enters login information
- Analysis available by selecting IMGT database version when adding a new analysis
- Uploads fastq files extracted from an NGS instrument
- Provides the setting function only detecting frequently analyzed loci by presetting

Analysis

Visualize

- Checks for the review contents and situation available on one screen through the 'view comments' function when confirming auto analyzed results of each locus
- Confirms detailed information through sequence viewer: coverage, locus structure, hetero region, etc.
- Confirms genotype test results: P group, G group, serotype provided
- Provides NGS sequencing QC and analysis QC results